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10/743,704	12/22/2003	Tim Keith	2976-4037US1	8966

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,704	KEITH ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-15,21,27 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-15,21,27 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 5/18/2007. Currently, Claims 1-9, 11-15, 21, 27, and 32 are pending. Claims 10, 16-20, 22-26, 28-31, and 33 have been cancelled.

2. The following rejections are applied as necessitated by amendment. Response to arguments follows.

3. This action for Claims 1-9, 11-15, 21-27, and 32 is FINAL.

Withdrawn Objections

4. The objection to Claims 13-15 and 20-21 made in Section 5 of the previous office action is moot in view of the amendments or cancellation of the claims.

Withdrawn Rejections

5. The rejection to Claim 21 under 35 USC 112/second paragraph made in section 6 of the previous office action is moot based on the amendments to the claims.

Terminal Disclaimer

6. The terminal disclaimer filed on 5/18/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US

Patent 6737519 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112/New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9, 11-15, 27, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claims contain subject matter that changes the scope of the claim and is not supported in the specification and raises issues of new matter.

Claims 1-9, 11-15, 27, and 32 were amended to the recitation "at least 289 consecutive nucleotides". This recitation is not supported in the specification and raises the issue of new matter.

Upon review of the specification, the specification does not appear to provide support for the recitation of "at least 289 consecutive nucleotides". In response to the amendment, applicants point to p. 11 lines 10-17 (p. 8 last paragraph) for support for the claim limitation "at least 289 consecutive nucleotides". However, the specification does not provide support for the specific nucleotide length of at least 289. The specification does provide support for the specific length limitation of 500 consecutive nucleotides on p. 5 lines 8-10.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 112-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9, 11-15, 21, 27, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to an isolated nucleic acid which may comprise at least 289 nucleotides of SEQ ID No. 2, 4, 6, 8, or 10 or a complement. Claims 2-3 define the nucleic acid. Claims 4-8 identify the vector or host cell. Claim 9 is drawn to at least 289 nucleotides of SEQ ID No. 2, 4, 6, 8, or 10 or a complement. Claims 11-15 define vector or host cell. Claim 27 is drawn to an isolated nucleic acid fragment comprising at least 289 consecutive nucleotide bases of SEQ ID No. 1. Claim 32 is drawn to a kit comprising a probe containing the nucleic acid sequence of claim 1.

It is noted that nucleic acids consisting of SEQ ID No. 2, 4, 6, 8, or 10 meet the written description requirements. However, none of the instant claims are limited to such a molecule. It is noted that "a complement" is being broadly interpreted as encompassing any fragment of SEQ ID NO. 2, 4, 6, 8, or 10 and not the full length of the claimed sequences. The claims as written encompass fragments of at least 289 mer of SEQ ID No. 2, 4, 6,8, 10, or 1, and any fragment of any length which is a complement of SEQ ID NO. 1, 2, 4, 6,8, or 10. Therefore the claims as broadly written encompass flanking sequences or unspecified length and identity.

The claims as broadly written encompass isolated nucleic acids comprising fragments of SEQ ID No. 1-2, 4, 6, 8, or 10 without any description of the nucleotides flanking the fragments. The specification does not provide an adequate written description of the claimed genus of nucleic acids as the claims are broadly written.

Additionally, the claims do not set forth the number or identity of nucleotides flanking the recited nucleic acid fragments. Accordingly, the claims encompass nucleic acids which comprise the recited 289 mer fragments of SEQ ID NO: 1, 2, 4,6, 8, 10 but

which do not share any overall level of sequence identity with the sequences. The variants may include nucleotide substitutions, additions, deletions, translocations and truncations. The claims thereby encompass naturally and non-naturally occurring allelic, mutant and splice variants of SEQ ID No. 1, 2, 4,6, 8, and 10.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID No. 1, 2, 4,6, 8, 10 will affect the functional properties of SEQ ID No. 1, 2, 4,6, 8, 10. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID No. 1, 2, 4,6, 8, 10) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID No. 1, 2, 4,6, 8, 10 having unspecified functional activities different from that of SEQ ID No. 1, 2, 4,6, 8, 10. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, and polymorphic sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the detection of ANY fragment of SEQ ID No. 1, 2, 4,6, 8, and 10.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The claims do not meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

The reply traverses the rejection. (A) The reply asserts that the phrase "a complement" clearly describes claims encompassing the complement of the full-length sequence or at least 289 or 500 consecutive nucleotides thereof (p. 8). (B) The reply asserts that there is sufficient written description of the nucleotides flanking the fragments on p. 5 lines 6-12 and p. 11 lines 10-17. (C) The reply asserts that the claims must comprise consecutive nucleic acids of defined sequences (p. 10 2nd to last paragraph).

These arguments have been thoroughly considered but have not been found persuasive.

(A) It is noted that the phrase "a complement" is broadly interpreted as encompassing not only "the complement" of the entire fragment, but also any fragment of the nucleic acid molecule. It is suggested that the claims be amended to "the complement" to encompass only the complement of the entire SEQ ID NO., or the complement of the at least 289 of the SEQ ID NO., or the complement of the at least 500 of the SEQ ID NO.

(B) Though the specification contemplates fragments of the instant SEQ ID Nos, the specification does not describe the fragments in such a way that the genus of

possible fragments can be determined. The specification does not describe the nucleotides flanking the fragments such that the skilled artisan would be able to determine which sequences that are encompassed by the broad claim language would have the function as SEQ ID Nos 1-2, 4, 6, 8 or 10. Therefore the claims encompass fragments with any number of possible mutations and variants flanking the regions of at least 289 wherein these possible nucleotides have not been described in the specification.

(C) The claims as amended are drawn to fragments of SEQ ID NO. 1, 2, 4, 6, 8, or 10 wherein the nucleotides flanking the fragments can include any number of variants in which the specification has not described which of the large number of potential sequences encompassed by the broad claim language will retain functionality.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4-5, 8-9, 11-12, 15 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AI126846 (NCBI website October 26, 1998).

With regard to Claim 1 and 9, GenBank Accession Number AI126846 discloses a sequence that comprises 292 contiguous nucleotides of SEQ ID NO. 4 (see alignment below wherein QY is the instant application's SEQ ID No. 4 and Db is GenBank Accession Number A1126846).

```
Qy       1122 TGGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACCTCAGACGATC 1181
             | ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         22 TAGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACCTCAGACGATC 81

Qy       1182 CACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGTGCCCGGCCAT 1241
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         82 CACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGTGCCCGGCCAT 141

Qy       1242 CATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAGAAACCCACTC 1301
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        142 CATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAGAAACCCACTC 201

Qy       1302 ATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACAGTGCTGGAAT 1361
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        202 ATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACAGTGCTGGAAT 261

Qy       1362 AAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGGTCAAA 1416
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        262 AAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGGTCAAA 316
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With regard to Claim 2, the nucleic acid sequence is DNA.

With regard to Claim 4, 5, and 11-12, GenBank Accession Number AI126846 discloses the fragments are in an expression vector (pT7T3D) and a host cell (DH10B) (Features Source).

With regard to Claim 8 and 15, GenBank Accession Number AI126846 discloses DH10B is the host cell, which is E. coli and therefore is a prokaryotic cell.

With regard to Claim 27, GenBank Accession Number AI26846 discloses a sequence that comprises 431 consecutive nucleotide bases of SEQ ID No. 1 (see alignment below wherein Query is GenBank Accession Number A1126846 and Sbjct is the instant application's SEQ ID No. 1).

```
Query  12    GTATTTTTAATAGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACC  71
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6699  GTATTTTTAATAGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACC  6758

Query  72    TCAGACGATCCACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGT  131
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6759  TCAGACGATCCACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGT  6818

Query  132   GCCCGGCCATCATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAG  191
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6819  GCCCGGCCATCATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAG  6878

Query  192   AAACCCACTCATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACA  251
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6879  AAACCCACTCATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACA  6938

Query  252   GTGCTGGAATAAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGG  311
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6939  GTGCTGGAATAAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGG  6998

Query  312   TCAAATGGTGACTTTACGTTTAACGTTCTGAGGAGCCGCCAGGCGTTTTAACACAGTGAC  371
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  6999  TCAAATGGTGACTTTACGTTTAACGTTCTGAGGAGCCGCCAGGCGTTTTAACACAGTGAC  7058

Query  372   TGCACCATTTCACATTCCTGCCAACAATGTGTGAGAATTCCAATTTCTCTACATCCCCAA  431
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  7059  TGCACCATTTCACATTCCTGCCAACAATGTGTGAGAATTCCAATTTCTCTACATCCCCAA  7118

Query  432   CATTTTCCTTT  442
             ||||||||||
Sbjct  7119  CATTTTCCTTT  7129
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10. Claims 1-5, 9, 11-12, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shankar et al. (Biochem. J. 1994 Vol 300 p. 295) as evidenced by GenBank Accession Number U14383 (NCBI website December 31, 1994).

Shankar et al. teaches a novel human airway mucin and disclose that this sequence is provided in the GenBank under the accession number U04799 (p. 295).

GenBank Accession number U04799 has been replaced by Accession No. U14383 (see Accession No. U14383).

With regard to Claims 1 and 9, GenBank Accession No. U14383 teaches a sequence which is 87.7% similar over the entire length to SEQ ID NO. 4, 82% similar to SEQ ID No. 2, 69.2% similar to SEQ ID Nos 6, 8, and 10. U14383 comprising at least 50 nucleotides which hybridize to SEQ ID No. 4, 2, 6, 8, and 10. U14383 comprising at least 50 nucleotides which hybridize under stringent conditions to SEQ ID No. 2, 4, 6, 8, and 10 (please see attached alignment of GenBank Accession No. U14383 with SEQ ID No. 2, 4, 6, 8, and 10) therefore GenBank Accession No. U14383 comprises "a complement" of SEQ ID NO. 2,4,6,8, and 10.

With regard to Claim 2, Shankar et al. teaches a nucleic acid sequence which is composed of DNA. With regard to Claim 3, GenBank Accession No. U14383 provides the amino acid sequence; therefore, the isolated nucleic acid that is at least 50 mer could be RNA.

With regard to Claims 4 and 11, Shankar et al. teaches placing the inset into a UniZap vector (expression vector) (p. 296 1st column 1st full paragraph). With regard to Claims 5, 8, 12, and 15 Shankar et al. teaches screening the library and selecting positive plaques (host cells) (p. 296 1st column 2nd full paragraph).

With regard to Claim 32, Shankar et al. teaches an RNAgents kit from Promega was used to isolate total RNA (p. 296 1st column last full paragraph). Shankar et al. teaches RNA samples isolated were transferred to a nylon membrane and probed with cDNA probes under high-stringency conditions which were labeled with a random

primer labeling kit (p. 296 1st column last full paragraph). Therefore, Shankar et al. teaches probes and hybridization reagents (random primer labeling kit).

Response to Arguments

The reply traverses the rejection. The reply asserts that Shankar et al. does not teaches the full-length or the complement of SEQ ID Nos. 2, 4, 6, 8, or 10 (p. 11 last paragraph and p. 12). The reply asserts that Shankar et al. does not teach at least 289 consecutive nucleotides of SEQ ID No. 2 or 4 or 500 consecutive nucleotides of SEQ ID No. 6, 8, or 10 (p. 11 last paragraph and p. 12).

These arguments have been fully considered but have not been found persuasive.

Though Shankar et al. does not teach a fragments comprising at least 289 consecutive nucleotides of 2 or 4, the claims are broadly interpreted as any fragment of any length of SEQ ID No. 2, 4, 6, 8, or 10. The claims are not limited to on the full-length complement. It is suggested that the claims be amended to "the complement" to remove the rejection of Shankar et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 6-7 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shankar et al. (Biochem. J. 1994 Vol 300 p. 295) as evidenced by GenBank Accession Number U14383 (NCBI website December 31, 1994) in view of Lasky et al. (US Patent 5304640 April 19, 1994).

Shankar et al. teaches a novel human airway mucin and disclose that this sequence is provided in the GenBank under the accession number U04799 (p. 295). GenBank Accession number U04799 has been replaced by Accession No. U14383 (see Accession No. U14383).

GenBank Accession No. U14383 teaches a sequence which is 87.7% similar over the entire length to SEQ ID NO. 4, 82% similar to SEQ ID No. 2, 69.2% similar to SEQ ID Nos 6, 8, and 10. U14383 comprising at least 50 nucleotides which hybridize under stringent conditions to SEQ ID No. 4, 2, 6, 8, and 10. U14383 comprising at least

50 nucleotides which hybridize under stringent conditions to SEQ ID No. 2, 4, 6, 8, and 10 (please see attached alignment of GenBank Accession No. U14383 with SEQ ID No. 2, 4, 6, 8, and 10).

Shankar et al. teaches placing the inset into a UniZap vector (expression vector) (p. 296 1st column 1st full paragraph). Shankar et al. teaches screening the library and selecting positive plaques (host cells) (p. 296 1st column 2nd full paragraph).

Shankar et al. does not teach human (eukaryotic) host cells.

However, at the time the invention was made, the transformation of human host cells with vectors comprising nucleic acids encoding human proteins was routing in the art. With regard to Claims 6-7 and 13-14, Lasky et al. teaches, "Typical eukaryotic host cells are mammalian, such as Chinese hamster ovary cells or human embryonic kidney 293 cells (Col. 11, lines 36-38)."

Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have transformed human host cells with vectors comprising the nucleic acid taught by Shankar et al. The ordinary artisan would have been motivated to create such host cells for the benefit of expression the polypeptide encoded by the nucleic acid taught by Shankar et al. in order to characterize and study the polypeptide.

Response to Arguments

The reply traverses the rejection. The response asserts that because Shankar et al. does not teach the limitations of Claim 1 and 9, the combination of Laskey et al. and

Shankar et al. does not encompass the limitations of the claims (p. 15 last paragraph). This argument has been fully considered but has not been found persuasive. As noted in the response to arguments presented for the 35 USC 102(b) as anticipated by Shankar et al., the claims can be broadly read as comprising complement of any size fragment of SEQ ID No. 2 or 4.

13. Claims 6-7 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AI126846 (NCBI website October 26, 1998) in view of Lasky et al. (US Patent 5304640 April 19, 1994).

GenBank Accession Number AI126846 discloses a sequence that comprises 292 contiguous nucleotides of SEQ ID NO. 4 (see alignment below wherein QY is the instant application's SEQ ID No. 4 and Db is GenBank Accession Number A1126846).

```
Qy       1122 TGGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACCTCAGACGATC 1181
              | ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         22 TAGAGACAGGGTTTCTCCTCATTGGCCAGGCTGGTCTCGAACTCCTGACCTCAGACGATC 81

Qy       1182 CACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGTGCCCGGCCAT 1241
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         82 CACCTGCCTCAGCCTCCCGAAGTGTTGGGATTACAGGCACGAGCCACTGTGCCCGGCCAT 141

Qy       1242 CATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAGAAACCCACTC 1301
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        142 CATTCCTTTTTACTGCTGACTAATAGTCTGCTGTGTGAATCCACCGCTAGAAACCCACTC 201

Qy       1302 ATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACAGTGCTGGAAT 1361
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        202 ATCAGTTGATGGTCATGTGGGTTGCTTCTGCTATTCGCTTATTATGAACAGTGCTGGAAT 261

Qy       1362 AAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGGTCAAA 1416
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        262 AAACGTTCCTGTGCACTCTTGGGCATACGCCTAGGAGTGGAACTGCTGGGTCAAA 316
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GenBank Accession Number AI126846 discloses the fragments are in an expression vector (pT7T3D) and a host cell (DH10B) (Features Source).

GenBank Accession Number AI126846 does not teach human (eukaryotic) host cells.

However, at the time the invention was made, the transformation of human host cells with vectors comprising nucleic acids encoding human proteins was routing in the art. With regard to Claims 6-7 and 13-14, Lasky et al. teaches, "Typical eukaryotic host cells are mammalian, such as Chinese hamster ovary cells or human embryonic kidney 293 cells (Col. 11, lines 36-38)."

Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have transformed human host cells with vectors comprising the nucleic acid taught by GenBank Accession Number AI126846. The ordinary artisan would have been motivated to create such host cells for the benefit of expression the polypeptide encoded by the nucleic acid taught by GenBank Accession Number AI126846 in order to characterize and study the polypeptide.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

JEANINE A. GOLDBERG
PRIMARY EXAMINER
8/2/07